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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,485	07/20/2001	Mark B. Lyles	068986.0102	1620

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EXAMINER
PAPPU, SITA S

ART UNIT	PAPER NUMBER
1636	7

DATE MAILED: 06/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/910,485	Applicant(s) LYLES, MARK B.	
	Examiner Sita Pappu	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 5-52 are pending in the instant application. IDS filed on 05/06/2002 (paper # 6) has been entered. This Office Action is in response to the communication filed by the Applicant on 05/06/2002 (paper #5).

Response to Amendment

Claims 1-4 are cancelled. Claims 5, 9-15, 18, 21-24, 27, 30, 31 are amended. New claims 34-52 are added. Currently, claims 5-52 are under consideration.

All rejections of claims 1-4 have been rendered moot in light of cancellation of these claims (paper # 5, filed 05/06/2002).

The rejection of claims 18-25 under 35 U.S.C. 103(a) is withdrawn in light of Applicant's amendment and arguments.

Claims 5-33 stand rejected and newly added claims 34-40, 42-46, 48, 50, 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Li, Y-X. (US patent No. 6,117,846) for reasons of record set forth in the office action mailed 01/29/2002 (paper #4) and as discussed, herein, below.

Claims 49, 51 and 52 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement.

Claims 49, 51, and 52 are rejected under 35 U.S.C. 112, second paragraph, for indefiniteness.

Response to Arguments

In response to the rejection of claims 5-33 under 35 U.S.C. 102(e), Applicant argues (page 9, bottom paragraph) that claims 5, 18, 27 have been amended to recite that the nucleic acids have an R-group substitution and that Li does not disclose the use of nucleic acids with R-group substitutions to reduce the absorption of ultraviolet radiation by the skin of a mammal or for the reducing sunburning or the occurrence of skin cancer.

These arguments have been considered but are not found persuasive.

The examiner agrees with the Applicant in that the teachings of Li et al. do not explicitly state that the nucleic acids used contain R-group substitutions, which in this case refer to methylated DNA as claimed in the amended claims 5, 18 and 27 of the instant case. However, Applicant's attention is drawn to the fact that Li et al. teach the use of porcine DNA (column 5, example 1, line 67), which is a vertebrate and it is known in the art that DNA of vertebrates is methylated (page 583, bottom paragraph, *In: Molecular Biology of the Cell by* Bruce Alberts *et al.* Second edition, 1989). Therefore, the methylated state is an inherent property of the porcine DNA taught by Li et al. and thus, Li et al. anticipate the use of nucleic acids with R-group substitutions to reduce the absorption of ultraviolet radiation by the skin of a mammal or for the reducing sunburning or the occurrence of skin cancer.

The intended use of the claimed composition is given patentable weight when making a determination of patentability under 35 U.S.C. 102 only when it serves to define a structural requirement. The intended use must result in a structural difference

between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Furthermore, the preamble is generally nonlimiting if it merely recites an inherent property. See MPEP 2111.02. In the instant case, the prior art structure has all the features required to perform the intended use recited in the claims. Furthermore, as there are no claimed distinguishing features between the claimed method of using the DNA of the instant case and that of Li et al., the methylated R-group substituions claimed are an inherent feature of the DNA. The claiming of a new use, new function, or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2112.

Thus, the claimed method of using the DNA composition is disclosed in the prior art.

New Grounds of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49, 51 and 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the

enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the Invention and the breadth of claims:

The claims are directed to a method of using a formulation of nucleic acid to reduce the absorption of ultraviolet radiation (claims 49 and 51)) and to a method of treating a skin condition exacerbated by ultraviolet radiation using the formulation of nucleic acid (claim 52). The claims encompass the use of the claimed method to block 100% of the ultraviolet radiation and treating a variety of skin conditions and are very broad.

State of the prior art, amount of guidance in the specification and working examples:

Prior art teaches that ultraviolet radiation can induce skin damage and further teaches that the damage can predispose one to conditions such as skin cancer. Prior art also teaches that sunscreens containing DNA can block the sunlight from reaching the skin of a subject. However, prior art does not teach sunscreens comprising DNA that can block 100% of the ultraviolet radiation. Nor does the prior art teach how a formulation comprising a nucleic acid can be used in a method of treating the skin

conditions claimed. In cases where prior art does not teach how to use the method, all the guidance for practicing the invention must come from the specification. The guidance in the specification is limited to the contemplation of the use of the claimed method to treat a variety of skin conditions caused by ultraviolet radiation (page 10, lines 13-31). The working examples demonstrate (pages 11-16) the percent transmission through solutions of herring sperm DNA of different concentrations in various buffers and various wavelengths. Other than this, the specification fails to teach that the formulation of the instant case can block 100% of the ultraviolet radiation and is therapeutically effective in treating the various skin disorders claimed. The specification fails to provide any correlative evidence between the method of the instant case and its ability to accomplish what is claimed. The specification fails to disclose how long the formulation of nucleic acids is effective in blocking the sunlight from reaching the skin of the mammal, and whether it is long enough to see a therapeutic effect. The working examples do not provide any guidance on how the effect of the formulation of nucleic acids on treating a mammal was measured and/or quantified, such that one of skill in the art would accept that their method would result in a therapeutic outcome and be able to practice the method using the guidance provided in the specification.

Predictability of the Art, Amount of Experimentation and Skill level of the artisan:

While it is relatively routine in the art to use nucleic acid containing formulations to reduce the absorption of sunlight at a level that is <100% and at non therapeutic levels, it is unpredictable without specific guidance and direction whether one will be able to bloch 100% of the ultraviolet radiation in any geographic region and whether the

formulation is effective in treating all the skin disorders claimed such that one of skill will be able to see a therapeutic effect. Thus, when there is deficiency in the art in terms of predictability of obtaining therapeutic levels of effectiveness, the Applicant must provide sufficient guidance and direction which demonstrates or reasonably correlates to therapeutic levels of effectiveness of a product in an art recognized animal model or patient as claimed.

Although the skill of an artisan in this subject area is considered to be very high, it would require undue experimentation on the part of an artisan to make and use the invention as specified and use the invention as claimed. The specification and the working examples do not provide sufficient guidance to practice the invention as claimed. Therefore, in the absence of specific guidance and working examples, the use of the claimed method to block 100% of the ultraviolet radiation in any geographic region and to treat all the skin conditions claimed is unpredictable. In such a situation, one skilled in the art would not know how to use the invention as claimed, without undue experimentation. In view of the limited guidance in the specification, and limited working examples, and the unpredictability of the art, one skilled in the art would be required to engage in undue experimentation, in order to use the invention. It is noted that the law requires that the disclosure of an application shall inform those skilled in the art how to use applicants' alleged discovery, not how to find out how to use it for themselves (see In re Gardner et al. 166 USPQ 138 (CCPA 1970). The specification only teaches what is intended to be done, but does not actually teach how to do that which is intended.

Thus, due to the art recognized unpredictability of blocking 100% levels of ultraviolet radiation in any geographis region and of achieving therapeutic levels of effectiveness, the lack of guidance provided by the specification, the lack of guidance concerning the treatment of various skin conditions using the claimed method, it would have required undue experimentation to practice the instant invention and the skilled artisan would not have predicted success in using the claimed method in blocking 100% of the ultraviolet radiation and in treating the various skin conditions claimed. Thus the specification does not enable one skilled in the art to use the claimed method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49, 51, 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 is indefinite in its recitation of "100% the ultraviolet radiation". Inserting an "of" before "the ultraviolet radiation" is suggested. Claim 51 is rejected insofar as it depends from claim 49.

Claim 52 is indefinite in its recitation of "erthematosis". Spelling correction is suggested.

Allowable Subject Matter

Claim 41 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 5-40, 42-46, 48-52 are not allowable.

Claim 41 is allowable if rewritten in independent form.

Claim 47 is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308 4242 for regular communications and (703) 872 9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

S. Pappu
June 3, 2002

REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
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